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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,160	02/28/2002	Shuji Kaneko	220125US0 X	4862

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,160	KANEKO ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18APR2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 9-14, and 21-36 are pending.

2. Claims 21-36 are rejected.

3. Claims 1, 2, and 9-14 are non-elected and withdrawn from consideration.

Response to Arguments

4. Applicants; arguments filed April 18, 2005 have been fully considered but they are not persuasive. First, applicants submit the following arguments that the instant claims are not anticipated, and for that matter rendered obvious, by the cited art of record because the compounds of formula (I) is specifically excluded by the instant claim language. Next, applicants submit that the prior art does not disclose or suggest the compounds used in the claimed methods.

5. First, applicants submit the following arguments that the instant claims are not anticipated, and for that matter rendered obvious, by the cited art of record because the compounds of formula (I) is specifically excluded by the instant claim language. However, the fact remains that Marston et al. of WO 98/27930 explicitly teach and disclose of the very same compounds that are instantly claimed. In addition, the compounds of Marston et al. of WO 98/27930 are not excluded from the instant claims. The skilled artisan would consider the potentiation of a N-type Ca^{2+} channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious,

since this property may be inherent in the prior art." For these reasons, the prior art reference of Marston et al. anticipates the instantly claimed subject matter.

6. Next, applicants submit that the prior art does not disclose or suggest the compounds used in the claimed methods. It appears that applicants have further elucidated an inherent biochemical mechanism with the administration of these already known compounds, as evidenced by Marston et al. of WO 98/27930. Marston et al. teach of the aminopiperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7). In addition, one having ordinary skill in the neuropharmaceutical art would consider the potentiation of a N-type Ca^{2+} channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." For these reasons, the prior art reference of Marston et al. renders the instantly claimed subject matter obvious.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The rejection of claims 21, 22, 26-28, and 36 under 35 U.S.C. 102(b) as being clearly anticipated by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998 is maintained and repeated for both the above-stated and reasons of record. Marston et al. teach of the aminopiperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7). The skilled artisan would consider the potentiation of a N-type Ca^{2+} channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art."

9. The rejection of claims 30-35 under 35 U.S.C. 102(b) as being clearly anticipated by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998 is maintained and repeated for both the above-stated and reasons of record. Claims 30-35 attempt to limit independent claim 21 by the incorporation of a product-by-process limitation on how the compound of claim 21 is obtained. In addition, these product-by-process limitations for claims 30-35 do not further limit the aminopiperazinyl compounds because these claims are defined as a product-by-process claim and is a product, not a process, see In re Bridgeford, 357 F2d 679, 149, USPQ 5 (CCPA 1966). It is the

patentability of the product claimed and not of the recited process steps which must be established, see In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Wertheim, 541 F2d, 191 USPQ (CCPA 1976). A comparison of the recited process with the prior art processes does not serve to resolve the issue concerning the patentability of the product, see In re Fessman, 489 F2d 742, 180 USPQ 324 (CCPA 1974). For these reasons, Marston et al. do in fact teach of the administration of aminopiperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). The skilled artisan would consider the potentiation of a N-type Ca^{2+} channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7).

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. The rejection of claims 21-29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Marston et al. of WO 98/27930 possessing a publication date of July 2, 1998 is maintained and repeated for both the above-stated and reasons of record. Marston et al. teach of the aminopiperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof for the treatment of inter alia schizophrenia, spinal cord injury, ADHD, narcolepsy and Parkinson's disease, (see pages 1-6). In addition, the prior art reference of Marston et al. specifically teach of oral or parenteral administration of the aminopeperazinyl compounds of formula (I) as well as its pharmaceutically acceptable salts thereof, (see page 7). Marston et al. further teach of various dosages of these compounds to mammals, (see pages 1, lines 6-13, page 3, lines 12-18 and page 7). The skilled artisan would consider the potentiation of a N-type Ca^{2+} channel activity as an inherent feature with the administration of these already known prior art aminopiperazinyl compounds. The courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." The instant method differs only in the specific range of dosages and modes of

administration. The determination of a dosage having the optimum therapeutic index while minimizing adverse or unwanted side-effects is well within the level of the skilled artisan, and the artisan would be motivated to determine optimum amounts as well as modes and methods of administration in order to get the maximum effect of the drug. Hence, the Marston et al. reference makes obvious the instant invention.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
May 16, 2005